

§ 522.1451

by or on the order of a licensed veterinarian.

[43 FR 59058, Dec. 19, 1978, as amended at 51 FR 741, Jan. 8, 1986; 53 FR 40728, Oct. 18, 1988; 62 FR 35076, June 30, 1997]

§ 522.1451 Moxidectin.

(a) *Specifications.* The drug product consists of two separate vials. One contains 10 percent moxidectin microspheres, and the other contains a vehicle for constitution of the moxidectin microspheres. Each milliliter of constituted, sustained-release suspension contains 3.4 milligrams (mg) of moxidectin.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use; dogs*—(1) *Amount.* 0.17 mg per kilogram body weight (0.0773 mg per pound) as a single subcutaneous injection.

(2) *Indications for use.* For prevention of heartworm disease caused by *Dirofilaria immitis*; for treatment of existing larval and adult hookworm (*Ancylostoma caninum*) and *Uncinaria stenocephala* infections.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[66 FR 35756, July 9, 2001, as amended at 67 FR 57944, Sept. 13, 2002]

§ 522.1452 Nalorphine hydrochloride injection.

(a) *Specifications.* Each milliliter of aqueous solution contains 5 milligrams of nalorphine hydrochloride.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* One milligram per 5 pounds; intravenously, intramuscularly, or subcutaneously.

(2) *Indications for use.* Respiratory and circulatory depression in dogs resulting from overdosage of, or unusual sensitivity to, morphine and certain other narcotics. Not for depression due to any other cause.

(3) *Limitations.* Successive doses of the drug gradually lose their analeptic effect and eventually induce respiratory depression equal to that of opiates. Therefore, do not exceed therapeutic dosage. Do not mix drug with meperidine solutions because the buffer will cause precipitation. Federal law

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restricts this drug to use by or on the order of a licensed veterinarian.

[44 FR 6707, Feb. 2, 1979, as amended at 47 FR 36418, Aug. 20, 1982; 62 FR 63271, Nov. 28, 1997]

§ 522.1462 Naloxone hydrochloride injection.

(a) *Specifications.* Naloxone hydrochloride injection is an aqueous sterile solution containing 0.4 milligram of naloxone hydrochloride per milliliter.

(b) *Sponsor.* See No. 060951 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used as a narcotic antagonist in dogs.

(2) It is administered by intravenous, intramuscular, or subcutaneous injection at an initial dose of 0.04 milligram per kilogram of body weight. When given intravenously, the dosage may be repeated at 2- to 3-minute intervals as necessary. Onset of action by intramuscular or subcutaneous injection is slightly longer than it is by intravenous injection, and repeated dosages must be administered accordingly.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 47 FR 20757, May 14, 1982; 54 FR 32632, Aug. 9, 1989; 63 FR 7701, Feb. 17, 1998]

§ 522.1465 Naltrexone hydrochloride injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 50 milligrams of naltrexone hydrochloride.

(b) *Sponsor.* See 053923 in § 510.600(c) of this chapter.

(c) *Conditions of use in elk and moose*—

(1) *Amount.* 100 milligrams of naltrexone hydrochloride for each milligram of carfentanil citrate administered. One-quarter of the dose should be administered intravenously and three-quarters of the dose should be administered subcutaneously.

(2) *Indications for use.* As an antagonist to carfentanil citrate immobilization in free-ranging or confined elk and moose (*Cervidae*).

(3) *Limitations.* Available data are inadequate to recommend use in pregnant animals. Avoid using during breeding season. Do not use in domestic food-producing animals. Do not use in free-ranging animals for 45 days before or during hunting season. Federal

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law restricts this drug to use by or on the order of a licensed veterinarian.

[62 FR 5320, Feb. 5, 1997]

§522.1468 Naproxen for injection.

(a) *Specifications.* The drug is a lyophilized powder which is reconstituted with sterile water for injection to form a 10 percent sterile aqueous solution (100 milligrams per milliliter).

(b) *Sponsor.* See 000856 in §510.600(c) of this chapter.

(c) *Conditions of use in horses.* (1) *Dosage.* Five milligrams per kilogram of body weight intravenously followed by maintenance oral therapy of 10 milligrams per kilogram of body weight twice daily for up to 14 consecutive days.

(2) *Indications for use.* For the relief of inflammation and associated pain and lameness exhibited with arthritis, as well as myositis and other soft tissue diseases of the musculoskeletal system of the horse.

(3) *Limitations.* Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 26763, May 15, 1981. Redesignated and amended at 51 FR 24525, July 7, 1986; 61 FR 5507, Feb. 13, 1996]

§522.1484 Neomycin sulfate sterile solution.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 50 milligrams of neomycin sulfate (equivalent to 35 milligrams of neomycin base).¹

(b) *Sponsor.* See No. 000009 in §510.600(c) of this chapter.

(c) *Conditions of use—*(1) *Amount.* 5 milligrams per pound of body weight daily divided into portions administered every 6 to 8 hours for 3 to 5 days.¹

(2) *Indications for use.* Administer to dogs and cats for the treatment of acute and chronic bacterial infections due to organisms susceptible to neomycin.¹

(3) *Limitations.* For intramuscular or intravenous use only. Neomycin is not for use parenterally in food-producing

animals because of prolonged residues in edible tissues. Labeling shall bear an appropriate expiration date. For use by or on the order of a licensed veterinarian.¹

[43 FR 48996, Oct. 20, 1978, as amended at 64 FR 403, Jan. 5, 1999]

§522.1503 Neostigmine methylsulfate injection.

(a) *Specifications.* Neostigmine methylsulfate injection contains two milligrams of neostigmine methylsulfate in each milliliter of sterile aqueous solution.

(b) *Sponsor.* See No. 000061 in §510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is intended for use for treating rumen atony; initiating peristalsis which causes evacuation of the bowel; emptying the urinary bladder; and stimulating skeletal muscle contractions. It is a curare antagonist.

(2) It is administered to cattle and horses at a dosage level of 1 milligram per 100 pounds of body weight subcutaneously. It is administered to sheep at a dosage level of 1 to 1½ milligrams per 100 pounds body weight subcutaneously. It is administered to swine at a dosage level of 2 to 3 milligrams per 100 pounds body weight intramuscularly. These doses may be repeated as indicated.

(3) The drug is contraindicated in mechanical, intestinal or urinary obstruction, late pregnancy, and in animals treated with other cholinesterase inhibitors.

(4) Not for use in animals producing milk, since this use will result in contamination of the milk.

(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 62 FR 61625, Nov. 19, 1997]

§522.1610 Oleate sodium solution.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 50 milligrams of sodium oleate.

(b) *Sponsor.* See No. 037990 in §510.600(c) of this chapter.

¹These claims are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter.